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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,992	05/09/2006	Jamieson W. M. Crawford	P-3522/26	4262

26253 7590 05/18/2007
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EXAMINER

THANH, LOAN H

ART UNIT	PAPER NUMBER
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3763

MAIL DATE	DELIVERY MODE
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05/18/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/538,992

Applicant(s)

CRAWFORD ET AL.

Examiner

LoAn H. Thanh

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 June 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the plurality of cannula finger lock (claim 6) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

The drawings are objected to because reference 165 disclosed in specification on page 10 has not been shown in the drawing. See fig.3A . Reference numeral 162 has been shown twice. The lead line of one could be made shorter to reference the sidewall and a reference 165 should be inserted with a longer lead line to show the bottom edge. See also figures 14A and 14B to make the same changes to make the drawings clear. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or

"New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "160" has been used to designate both slot and top wall. See figures (figs.) 3A,15A (slot) and figs. 14a , 14b (top wall).

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "190" has been used to designate both touch bumps and gel material. See figs. 1,2,6,10,13 (touch bumps) and fig. 16 (gel material).

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities: Applicant is suggested to be consistent with reference numeral 190. For example, see page 12, lines 27 and page 15, line 9.

The lengthy specification has been checked but has not been checked to the extent necessary to determine the presence of *all possible minor errors*. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-4, 11-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites the limitation "said portions of said needle cannula" in line 4. There is insufficient antecedent basis for this limitation in the claim. There is only antecedent basis for portions of the cannula finger lock.

Claim 4 recites the limitation "said portions of said needle cannula" in line 4. There is insufficient antecedent basis for this limitation in the claim. There is only antecedent basis for portions of the cannula finger lock.

Claim 11 recites the limitation "said portions" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 12 recites the limitation "said portions of said needle cannula" in line 4. There is insufficient antecedent basis for this limitation in the claim. There is only antecedent basis for portions of the cannula finger lock.

Claim 13 recites the limitation "said portions of said needle cannula" in line 4. There is insufficient antecedent basis for this limitation in the claim. There is only antecedent basis for portions of the cannula finger lock.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3,7, 10-12, 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Irisawa (US 5,885,249).

Irisawa discloses a shield/cap which is hingedly and rotatably connected to a needle hub . The shield has at least one cannula finger lock with a wide rigid base which is connected to the sidewall and has a reduced dimension as it extends away from the sidewall. See figures 1-2, 9-22,25-26 and specifically 23-24. It is considered by the Examiner that the reduced dimension is apparent in the transverse direction with respect to the needle 20.

Claims 1-3, 7,9, 10-12, 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Gyure et al. (US 5,665,075).

Gyure et al. (hereinafter referred to as Gyure) discloses a shield which is hingedly and rotatably connected to the needle assembly. The cannula finger lock shown in figure 5 is unitarily formed with the shield and also has a reduced dimension in the transverse direction. Further, the shield has ears (64,65 or 86,87) which are considered to engage with detent on the distal end of the hub. See figs. 1-5, 7-8 and columns 3-8.

Claims 1,2,4,7,9-11,13,16 are rejected under 35 U.S.C. 102(b) as being anticipated by Orgain (US 5,188,611).

Orgain discloses a shield having a cannula finger lock (see fig. 15) which has a reduced dimension near the free end . Further, the cannula finger lock has a dimension which is reduced in the parallel direction. The term "proximity to " is given the broadest interpretation. Also, the ear 97 on the shield engages with the at least one detent (98) on the hub.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hollister (US 5,139,489) in view of Irisawa (US 5,885,249) or Orgain (US 5,188,611) or Gyure et al. (US 5,665,075).

Hollister discloses the invention as substantially claimed. Hollister teaches a needle 26 mounted to a hub 6 having a proximal end projecting beyond the hub 6. Hollister also teach withdrawing fluids and protecting the needle. Hollister further teaches a shield hingedly connected and mounted to the hub 6 wherein the shield has cannula finger locks which extend from the top wall. However, Hollister does not teach the cannula locks extending from the sidewall. Irisawa or Orgain or Gyure et al., individually, teach a needle connected to a syringe capable of withdrawing or injecting fluid and protecting the needle. Each reference teaches a shield with at least one cannula finger lock which extends from the sidewall for protecting the needle or patient from needle sticks. It would have been obvious to one of ordinary skill in the needle shielding art to modify the cannula finger lock of Hollister with a cannula finger lock which extends from the side wall as taught by Irisawa or Orgain or Gyure et al. in order to provide an alternate method of manufacturing with less material or an alternate locking system which performs the same function.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10, 13-23 of copending Application No. 10/488,811 (US 2005/0124944) and over claims 1-9,12-19 of 11/609,441 (US2007/0106224). Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the claims of the present application are similar to the claims of 10/488,811. (The similar limitations are the shield with the cannula finger locking members which has a rigid base and a flexible free end, the hingedly connection of the shield to the needle hub and the web/gaps).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-2,7-9,10-11,16 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-4, 6-8,10-11,30-31 of 10/156,611 (US2005/0245879) now U.S. Patent No. 7,223,258. Although the conflicting claims are not identical, they are not patentably distinct from each other

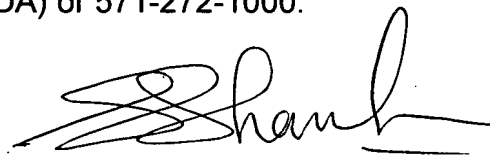
because they claim similar limitations such as the shield with the cannula finger locks/cannula shelf lock which has reduced dimensions providing a free end, the shield further hingedly connected to the needle hub).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is (571) 272-4966. The examiner can normally be reached on Mon. - Fri. (First Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



LoAn H. Thanh

**LOAN H. THANH
PRIMARY EXAMINER**

